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Approved by:

Garth Thorburn, Agricultural Attaché
Office of Agricultural Affairs

Prepared by:

Oleksandr Tarashevych, Agricultural Specialist

Report Highlights:

The current regulatory process for the approval of biotech crops in Ukraine is not well defined and is based on registration procedures designed for conventional plant varieties. Efforts to establish a more efficient biotechnology regulatory framework stalled in Parliament in 2002. Since there have been no biotechnological varieties approved or registered in Ukraine, the government considers Ukraine free of biotech products. Some doubt exists to that claim.

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Executive Summary

Imports of food and agricultural products to Ukraine totaled \$2.6 billion (CIF value) in 2005. United States captured 4% (\$107 million) of the import market with poultry meat, fish, tobacco, planting seeds, soybean meal, pet food, proteins derived from soybeans and tree nuts being the major US food and agricultural items exported to Ukraine. According to FAS-Kiev estimates, the value of U.S. soybean meal, soy proteins and isolates, corn products, planting seeds and other products that faced or could have encountered trade restrictions because of unclear biotechnology regulations ranged from **\$1.1 million (2003)** to **\$12.9 million (2005)**. Issues of market access for products of agricultural biotechnology are expected to become more critical as Ukraine will increase its oilseed processing capacity and will probably enforce labeling regulations for genetically modified products.

Ukraine has a number of biotechnology policy issues that impact trade. Lack of legislation that would establish a biosafety regulatory framework hinders registration of biotech crops. Unclear food labeling regulations for genetically modified organisms and the great degree of latitude exercised by various regulatory officials at the border do not encourage fair competition. Uncertainty over implementation of the Cartagena Protocol will discourage imports of bulk agricultural commodities.

The Ukrainian government (GOU) authorized field trials of biotech crops along with an environmental and food safety assessment in 1998. Insect resistant (Bt) potatoes and herbicide tolerant sugar beets, corn and rapeseed underwent full-scale field trials in 1998-2000. None have received final approval, however, due to the unwillingness of decision-making authority to take full responsibility for the approval of these products, especially since Ukraine has no established system for approving biotech varieties. There have been no new applications for registration of biotech crops since then because of uncertainty over the length of the approval process and uncertainty over the final result. Ukraine has no functioning biosafety regulatory framework at this point. Draft legislation that would delegate regulatory authority to relevant GOU agencies has been pending final approval by the Ukrainian Parliament since November 2002.

In the future, Ukraine will most likely adopt biotechnology policies that mirror those applied in the EU. However, there is a possibility that the Ukrainian government will allow the agricultural industry, consumers and the environment to benefit from biotech products considering the remote possibility of EU membership.

There are some in the government of Ukraine that see the benefit biotech products can bring to Ukrainian agriculture. These officials and scientists are attempting to persuade key policy makers into approving the legislation on agricultural biotechnology. It's unknown if they will succeed, but there seems to be a growing acceptance on the benefits of biotechnology.

Section II. Biotechnology Trade and Production.

Production

Ukraine has not approved a single biotechnology crop for commercial production despite having received five applications in 1997-1999. Therefore, authorities claim that Ukraine's agriculture remains GMO-free. A weak regulatory system, the lack of field surveillance programs and laboratory capacities, however, leave doubt to Ukraine's GMO free status.

Ukrainian researchers in cooperation with a Russian scientist reportedly developed potatoes resistant to the X-virus in 1990. This was the first transgenic plant in the Former Soviet Union (FSU). Since then, research in this area has continued in the Institute of Cell Biology

and Genetic Engineering (ICBGE) of the National Academy of Sciences of Ukraine, and Institutes of the Ukrainian Academy of Agricultural Sciences. According to available information, Ukrainian researchers developed transgenic sugar beets, potatoes, tobacco, rapeseeds, cabbage, alfalfa, soybeans, peas, flax, barley, buckwheat, and African millet. Most of these plants were developed for scientific purposes using non-patented technologies and utilized germplasm of the local varieties to gain insect resistance or herbicide tolerance.

Reportedly, scientists from the ICBGE developed transgenic soybeans, flax and African millet with *dinitranilin* resistant features (*Treflan* and other herbicides produced by DowAgro Sciences Co.) However, the technology has not yet been patented. All plants remain in the laboratory environment and have gone through the seed propagation stage. Ukrainian scientists also developed technology for plant recombinant proteins used in pharmacology -- α -interferon and somatropine (human growth hormone). However, this technology has not yet been commercialized.

Trade Impact

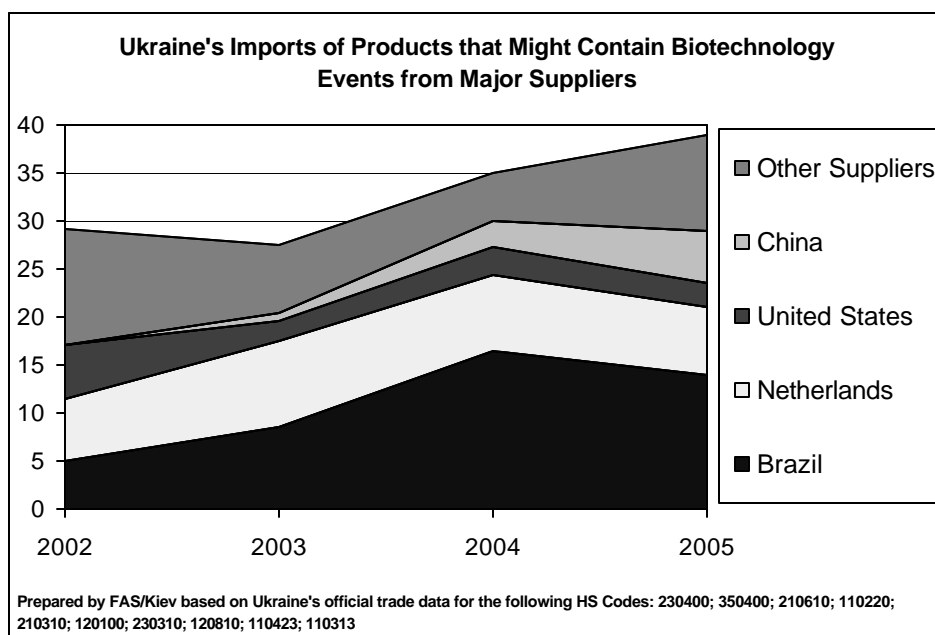
The lack of an established and operational biotechnological regulatory framework in Ukraine impacts trade as some regulatory officials use biotechnology as a justification for trade restrictions. The Ukrainian Veterinary Service tried to use the issue of "genetically modified feeds" used in poultry feed in the United States as a reason to block trade in poultry meat in 2002. This issue was discussed and eliminated during negotiations between the USDA and the State Department of Veterinary Medicine of the Ministry of Agricultural Policy of Ukraine in March 2003.

On occasion, local food safety officials have been known to demand from traders proof that imported commodities, mainly soybeans and soybean meal, are GM free. This occurs despite the fact that there are no official regulations banning the import of GM feed products.

In September 2000, a joint order from the Ministry of Agricultural Policy of Ukraine and the Ukrainian Academy of Agricultural Sciences (UAAS) prohibited the importation of honey and bee products that were byproducts of "bees fed with GMO-containing feeds". Although scientific justifications that support this measure do not exist, the order remains in effect. This order points to one of the major weaknesses of the Ukrainian regulatory system -- involvement of non-regulatory agencies in the decision making process.

FAS-Kiev summarized data on Ukraine's imports of the following major products that might contain biotech corn or soybean events: Corn Flour (HS 110220); Corn Meal or Groat (HS 110313); Worked Corn (HS 110423); Soybeans (HS 120100); Soy Sauce (HS 210310); Protein Concentrates (HS 210610); Corn Gluten (HS 230310); Soybean Meal (HS 230400); Protein Isolates (HS 350400). Prepared food products and feeds were not targeted in this research.

Ukraine imported products valued at \$39 million in 2005 that could contain GMOs. Surprisingly, the United States appears to be only the third largest supplier of these products after Brazil and the Netherlands, Ukraine's major suppliers of soybean meal (see the graph below).



The following table illustrates U.S. exports of food and agricultural commodities that are affected, or might be affected, by Ukraine's biotech regulations in the future.

Imports of U.S. Products that Could be Affected by Ukraine's Biotech Regulations (CIF, \$1,000)

HS Code	Description	2003		2004		2005	
		Value \$1,000	Share %	Value \$1,000	Share %	Value \$1,000	Share %
230400	SOYBEAN MEAL	237	21%	1,184	51%	173	1%
350400	PEPTONE, PROTEIN ISOLATES	426	37%	1,040	45%	1,753	19%
210610	PROTEIN CONCENTRATE	12	1%	53	2%	477	14%
120100	SOYBEANS	64	6%	44	2%	29	58%
210310	SOY SAUCE	10	1%	14	1%	23	7%
230310	CORN GLUTEN	404	35%	0	0%	0	0%
110423	WORKED CORN	0	0%	0	0%	0	0%
Total		1,155	100%	2,335	100%	3,171	100%

Data source: State Statistics Committee of Ukraine

The future impact of trade in biotechnology, however, should not only be guided by the information provided in the table above. One new crushing plant capable of crushing soybeans is scheduled to begin operations in the Port of Illichivsk (near Odessa) in MY 2005/2006. Although, currently there are no plans for import of soybeans for crushing, it is highly probable that soybeans will be imported in the future assuming favorable crushing margins and the existence of clear regulations governing imports of GM soybeans. Imports of 50,000 MT of soybeans may increase the value of trade that is subject to biotech regulations by **\$13 million**.

Issues related to the presence of biotechnology products in food assistance programs are not expected to have any significant importance in the future. The Ukrainian government and non-government organizations received agricultural products under various U.S. food assistance programs in 1995-2000. Since then, the country has not faced problems with

commercial food imports, hard currency shortages or foreign exchange. Ukraine is by far a net food exporter and will not likely require any food assistance in the future.

Section III. Biotechnology Policy

Ukraine is in the process of developing its national biosafety regulatory system. Currently, there is no legislation in place to govern environmental, food or feed safety assessments of GMOs. The country, however, developed legislation to require GMO food labeling, signed the Cartagena protocol and has provisional procedures for biotech crop registration.

In response to the first application to register a biotech crop, the Cabinet of Ministers of Ukraine approved provisional procedures for testing GM crops in 1998 and authorized the State Service on Protection of Plant Variety Rights under the Ministry of Agricultural Policy of Ukraine to coordinate this process. The Interagency Biosafety Commission under the Ministry of Science and Education of Ukraine reviewed the initial application from the companies and conducted an environmental risk assessment. Five biotech crops (see the table below) underwent field trials in 1997-2000. However, due to the absence of a legislative framework and unwillingness of the State Service on Protection of Plant Variety Rights to take the responsibility, none has received final approval.

Genetically Modified Crops That Went Through Field Trials in Ukraine.

Trait	Crop	Number of varieties	Applicant	Year of application	Status
BT (insect resistance)	Potatoes	3	Monsanto	1997	Pending
Glyphosate tolerance (Liberty Link)	Sugar beets	1	Syngenta/Monsanto	1998	Pending
BT (insect resistance)	Corn	1	Syngenta	1998	Pending
Glyphosate tolerance (Liberty Link)	Rapeseed	1	Bayer	1998	N/A
Glyphosate tolerance (Roundup)	Corn	1	Monsanto	1998	Pending

The current regulatory process for approval of biotech crops in Ukraine is very cumbersome. It is based on mandatory registration procedures designed for conventional plant varieties. However, a biotech plant variety is required to go through a more rigid and lengthy registration process than a variety using conventional plant breeding. According to provisional procedures that are still in place, legal steps necessary for registering biotech crops are outlined in Appendices A and B.

The Draft Law of Ukraine "On the State Biosafety System for Developing, Testing and Usage of Genetically Modified Organisms", which was prepared to address the legislative vacuum, passed the first reading in the Ukrainian Parliament in November 2002. The Law has been pending final approval by Parliament since then. According to the proposed legislation, regulatory responsibilities will be divided amongst the Ministries of Education and Science (MES), Environment and Natural Resources (MENR), Health Care (MHC), Agricultural Policy (MAP) and a special regulatory agency - Interagency Commission on Biosafety (ICB). Once the law is adopted, these regulatory agencies will develop implementing regulations. The authority of each regulatory agency as specified in the draft law is outlined in Appendix C.

Ukraine has not approved any biotechnology crops for food, processing or feed as there are no applicable regulations governing food or feed safety assessment of GMOs.

It is not yet clear how the Ukrainian regulatory system will treat "stacked" biotechnology events (plants that combine two already approved traits, such as herbicide tolerance and insect resistance). The biotech event will require only one registration with the Interagency Biosafety Commission in accordance with the yet-to-be-approved draft biosafety legislation.

However, agricultural authorities in charge of plant variety rights protection will most likely require a separate registration for each new variety that contains a new trait.

The domestic organic farming industry is just beginning to develop; therefore, there are no official or industry organic standards at this point. Some Ukrainian farms were certified as organic by EU-based institutions. Peaceful coexistence between organic and biotech crops in Ukraine is unlikely. Organic soybean producers in Ukraine have already called for a ban on GM crop plantings.

Labeling

While there are no labeling requirements applicable to biotech feeds, Ukraine's current GMO labeling rules represent one of the major uncertainties for food importers. Food products that contain GMOs were not regulated prior to October 24, 2002, the date when the Parliament of Ukraine incorporated changes into the Law of Ukraine On Food Safety. The legislation included food products that contain "genetically modified components" to the category of new food products along with newly developed foods, products that have not been imported before, products that contain new components/ingredients and products that were produced using new technology. A separate line on the presence of GMOs in food products was included to the list of mandatory information to be provided on the label. It appears that any quantity of GMOs must be labeled according to the Law.

This legislation was adopted to reflect the consumers' "right to know" because the GOU does not conduct food safety risk assessments for GMOs at this point. The current labeling legislation is unclear on label language, placement or threshold. The implementing regulations entitled "On Approving Rules of Retail Trade in Food Products" adapted by the Ministry of Economy of Ukraine on July 23, 2003 did not clarify these issues. The regulations simply prohibited the sale of domestically produced and imported consumer packaged food products that do not have an "easy to comprehend" label. Unofficial tests of consumer-ready products conducted by Ukrainian labs capable of identifying selected GM components revealed possible presence of GM components in some products are readily offered for sale in Ukraine. So far, the domestic food industry and food importers are not labeling GM products due to the lack of clarity in the requirements.

Biosafety Protocol

Ukraine ratified the Protocol on Biosafety to the Convention on Biological Diversity on September 12, 2002 (the Cartagena Protocol). Ratification of the Protocol has not resulted in the development and implementation of a comprehensive biotechnology regulatory framework in Ukraine. The Ministry of Environment and Nature Protection of Ukraine is expected to take the lead in the implementation of the Cartagena Protocol. The Ministry has undergone several reorganizations in the past few years. Diverging interests from other GOU agencies have also been a stumbling block to the development and implementation of Biosafety Legislation. It is unclear, at this point, how the new Ukrainian government will implement the requirements of the Protocol.

Section IV. Marketing Issues

There are no studies on potential market acceptance related to the sale of biotechnology products in Ukraine. As consumer incomes in Ukraine rise, the country is expected to increase imports of processed and consumer ready food products from the United States and other countries. Enforcement of GMO labeling requirements or possible adoption of EU labeling and traceability regulations would have a major negative impact on both domestic and imported food sales. Consumers in Ukraine tend to carefully analyze the contents on the

label. There is a widespread belief amongst consumers that products that contain food additives are not healthy. Therefore, consumers will exercise great caution in purchasing products with the "contains GM components" mark on the label.

Enforcement of GM labeling of food products will likely harm U.S. exports of soy-based ingredients used by local meat processors and other food producers. Feed producers, however, are not going to change their purchasing decisions as these will likely continue to be determined by price level and not what's on the label. As part of Ukraine's commitments under the Cartagena Protocol, documentation requirements for custom clearance of soybeans or other bulk commodities are expected to have a greater impact on oilseed processors and feed producers than food labeling requirements.

Due to frequent regulatory changes in Ukraine, U.S. exporters are reminded to check with their importers on applicable regulations and documentation requirements prior to exporting to Ukraine. Interested exporters may learn more about food and agricultural imports regulations and standards by downloading the following report prepared by FAS-Kiev <http://www.fas.usda.gov/gainfiles/200508/146130466.pdf>

Section V. Capacity Building and Outreach

U.S. government agencies have conducted a number of outreach activities targeted on creation of an effective and transparent biotechnology regulatory framework.

In May 2006 the Black Sea Biotechnology Association with financial support from the Ukrainian Academies of Science and other organizations held an international symposium in Yalta from May 10 – 14, 2006, on agricultural biotechnology research, regulatory policies, and public perception. A broad range of speakers talked on topics including basic science research, global biotech crop adoption, global regulatory policies, international organizations working on biotechnology capacity building, and the biotech's economic impact on countries in the region. The conference audience comprised scientists and others with an interest in biotechnology. Government officials from some of the Black Sea countries, especially Ukraine and Russia, were also present but they mostly held advisory positions rather than being key policy decision-makers. Symposium materials were posted on the All-Ukrainian Association of Plant Biologists web site <http://www.auapb.org/eng/pageseng/5.htm>

FAS-Kiev facilitated an International Seminar on Biosafety in November 2003. Two professors from UC Davis traveled to Ukraine to make presentations on the U.S. regulatory system and, vertical and horizontal gene flow. Scientists from Great Britain and Switzerland made presentations on public debates over GM foods and genomics. Approximately 50 scientists, graduate students and regulators from various Ukrainian research institutes and regulatory agencies representing 20 of the 25 Ukrainian oblasts were present, providing excellent regional coverage. All presentations from this seminar were posted on <http://www.auapb.org/eng/pageseng/5.htm>.

Since the seminar took place well in advance of the final review of the draft biotech law, scientists from the National Academy of Sciences of Ukraine had an opportunity to provide comments and suggestions on the current draft law to the responsible Parliamentary Committees. However, Parliament's Committee for Science and Education has not made proposed changes to the draft legislation public before the final voting of the Law.

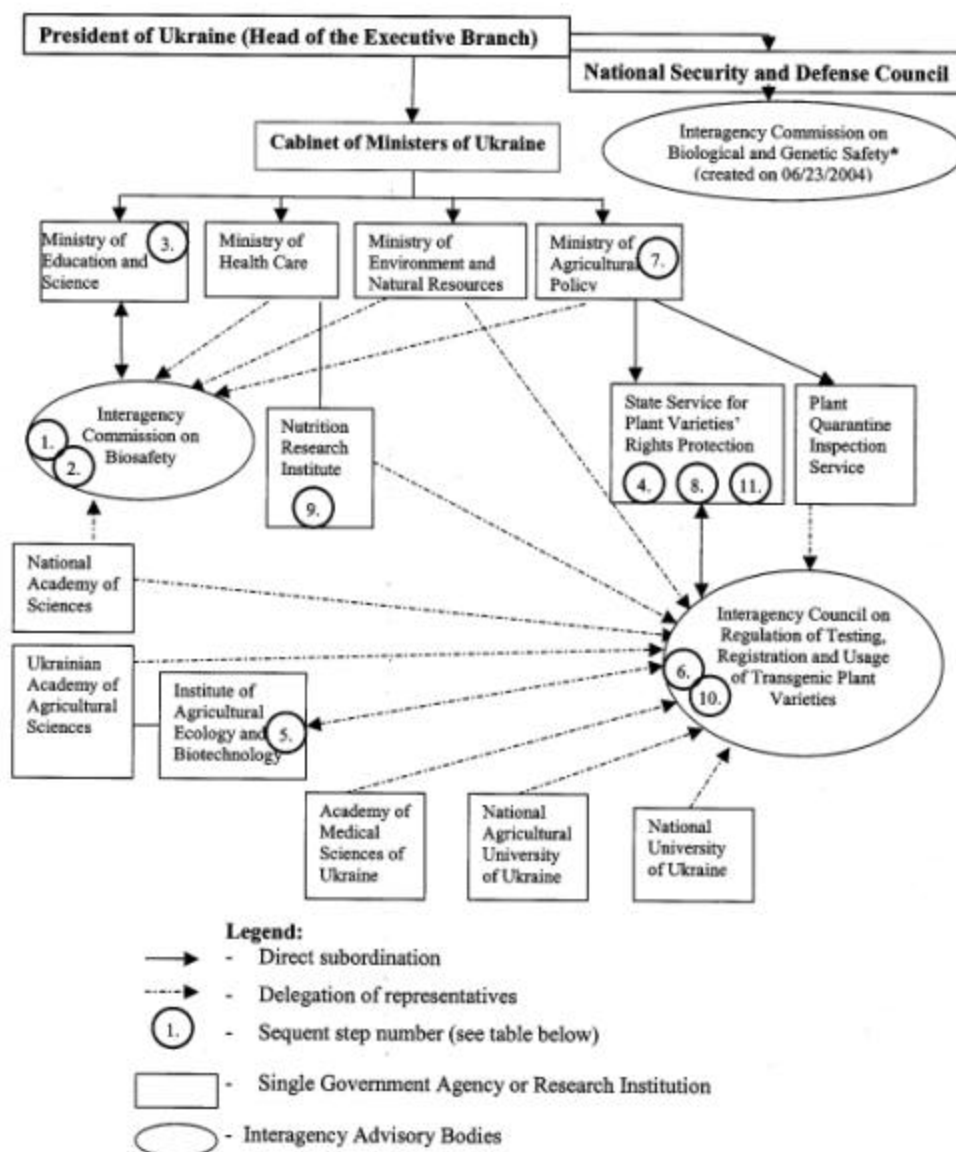
In 2002, four Ukrainian scientists from the State Service on Plant Variety Rights Protection of the Ministry of Agricultural Policy, Institute of Ecohygiene and Toxicology of the Ministry of Health Care, Institute of Cell Biology and Genetic Engineering of the National Academy of Sciences and the Ukrainian Academy of Agricultural Sciences participated in a two-week

training program under the Cochran Fellowship Program. The program helped to educate key Ukrainian researchers on the roles played by USDA, Food and Drug Administration and Environmental Protection Agency in the U.S. coordinated biotechnology regulatory framework as well as to provide more detailed information on APHIS biotech regulations.

The Department of State invited two Ukrainian scientists, two regulators and one journalist on the program entitled "Agricultural Biotechnology for Sustainable Development" in 2000 under the International Visitors Program. This was the first opportunity in Ukraine to study the U.S. biotechnology regulatory system. The trip helped in preparing the initial draft of Ukraine's biosafety law and provided an excellent opportunity to initiate a series of well-balanced articles on agricultural biotechnology (<http://www.zerkalo-nedeli.com/nn/show/419/36760/>; <http://www.zerkalo-nedeli.com/nn/show/317/28987/>; <http://www.zerkalo-nedeli.com/nn/show/372/33134/>). "Dzerkalo Tyzhnya" Weekly, one of the most reputable Ukrainian newspapers published articles and also hosted an electronic round table with participation of scientists from the U.S. Agency for International Development <http://www.zerkalo-nedeli.com/nn/show/317/28987/>. Articles and the transcript of the round table are available in Russian.

Appendices

Appendix A. The Scheme of Ukraine's Biotechnology Regulatory Process As It Currently Applies to Biotech Crops.



Prepared by FAS-Kiev based on available Ukrainian Regulations and interviews with industry experts.

Appendix B. Steps Necessary To Register a Biotech Crop in Ukraine

Phase	Step	Description	Responsible Agency	Required time
State Registration of the GMO	1	Application for GMO's environmental release and registration (The GMO must meet the two following criteria: absence of hazard for human health and the environment (if used as intended); identifiability)	Interagency Commission on Biosafety (ICB) (currently under the Ministry of Science and Education of Ukraine. According to the Draft Biosafety Law, ICB will report directly to the Cabinet of Ministers of Ukraine)	270 days
	2	The ICB conducts environmental risk assessments and issues one of three possible verdicts: a. - release of the GMOs into the environment is safe; b. - release of the GMOs into the environment is safe subject to specific requirements; c. - release of the GMO into the environment is potentially unsafe	ICB	
	3	The GMOs that received a or b-type verdicts (step #2) are to be included into the State Register of the GMOs*.	ICB, Ministry of Education and Science	
Import Permit for Testing	4	Application to import GMP plants for variety testing	State Service for Plant Varieties Rights Protection under the Ministry of Agricultural Policy of Ukraine (SSPVRP/MAPU)	Unknown
	5	Application is forwarded for an examination	Institute of Agricultural Ecology and Biotechnology, Ukrainian Academy of Agricultural Sciences	Unknown
	6	Supporting letter is sent to the Ministry of Agricultural Policy	Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties of the SSPVRP/MAPU	Unknown
	7	Import permit for testing is issued	Ministry of Agricultural Policy of Ukraine	30
Testing	8	Usual State Plant Variety Testing Program under control of the Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties	SSPVRP/MAPU	2-3 years
	9	GM samples are sent for a food safety assessment	Nutrition Research Institute under the Ministry of Health Care of Ukraine	Unknown
	10	Approval of the GM variety subject to favorable test results (steps 9-10)	Interagency Council on Regulation of Testing, Registration and Usage of Transgenic Plant Varieties of the SSPVRP/MAPU	Unknown
Final permit	11	Entry of the GM plant variety into the State Register of Plant Varieties of Ukraine Note: Although, GM plant variety testing is to be conducted the same way as for conventional varieties, GM varieties have to be included into a separate section of the State Plant Varieties Register	SSPVRP/MAPU	Unknown
Estimated minimum time required				3-4 years

* Presidential Degree established Interagency Commission on Biological and Genetic Safety under the National Security Council of Ukraine on 06/23/2004. It is yet another advisory body responsible for biosafety issues. It is expected, however, that this Commission will pay more attention to bioterrorism-related problems.

Appendix C. Agency Responsibilities As Per the Draft Law of Ukraine “On the State Biosafety System for Development, Testing and Usage of Genetically Modified Organisms”.***Interagency Biosafety Commission***

- promote implementation of state policy in the area of safe usage of the GMOs;
- provide advice to central executive agencies, entities involved in genetic engineering and public organizations on safe use of the GMOs;
- coordinate the actions of central executive agencies and scientific institutions in the area of safe use of GMOs;
- draft regulations on genetic engineering in accordance with the development of scientific knowledge and develop proposals on improving existing regulations;
- develop criteria for assessing the risk of potential environmental impact of GMOs;
- develop and improve a system of controlling compliance with genetic engineering safety requirements;
- consider applications for the release of GMOs into the environment by examining documents submitted by the applicant and engaging institutions authorized by the commission in such examination;
- organize, if necessary, limited pre-registration testing of GMOs by institutions authorized by the commission;
- issue conclusions as to the possibility of release and registration of GMOs;
- ensure control over safety of genetic engineering and during release of GMOs into the environment;
- perform registration of genetic engineering works of risk levels 3 and 4
- inform the public about genetic engineering activities performed in Ukraine and biosafety measures that are in place;
- participate via other government agencies in cooperation with international organizations.

Ministry of Environment and Nature Protection

- environmental risk assessment of GMOs via its representatives in the Interagency Biosafety Commission under the Cabinet of Ministers of Ukraine;
- exercise state supervision and control over the practical use of GMOs;
- carry out long-term monitoring of the potential impact of GMOs to the environment;
- exercise control over biosafety measures during GMO testing;
- information dissemination, education and participation of the public in ensuring sustainable use of biological diversity;
- within its powers, issue regulations necessary to ensure enforcement of this Law.

Ministry of Health Care of Ukraine

- perform state sanitary and hygienic examination and registration of foodstuffs, biologically active food supplements, cosmetic and pharmaceutical products and other products intended for direct human consumption, which contain GMOs.
- perform necessary tests of GMOs used in the production of foodstuffs, biologically active food supplements, cosmetic, pharmaceutical products and other products in order to ensure protection of human health;

Ministry of Agricultural Policy

- ensure state testing and registration of GMO-based crop varieties, animal breeds, microbiological agricultural and veterinary preparations and crop protection means via its agencies;
- ensure control over compliance with safety requirements when performing genetic engineering activities in agricultural enterprises, institutions and organisations irrespective of subordination and ownership;

Ministry of Science and Education

- develop research potential in the area of genetic engineering;
- registers the GMO and maintains a special GMO register.
- Protects national and international patents in the area of genetic engineering.